K012316

AUG 2 3 2001

510(k) Summary

Trade Name: **PermaCem / PermaCem Dual**

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901

Registration # not yet assigned

Device Generic Name: Dental luting material

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices:

Product Name	510(k) #	Manufacturer
Advance	K 940914	Dentsply Int'l.
Optibond	K940513	Kerr Mfg. Co.
C&B Luting Composite	K940030	Bisco
Flexi-Flow	K922249	EDS
C&B Metabond	K960464	Parkell
Duolink	K943596	Bisco
Variolink	K931309	Vivadent
Dyract Cem	Unknown	Dentsply
Fuji Duet (Fuji Plus)	K946100	GC
Resinomer	K924151	Bisco
Cement-It	Unknown	Jeneric/Pentron Inc.
ABC Dual Adhesive Bridge Cement	Unknown	Vivadent

Product Description:

PermaCem:
PermaCem is a chemical-curing, radiopaque two-component luting material available in automix delivery systems or as a handmix material, designed for the permanent luting of metals, ceramics, and resin-based materials, which may be luted to tooth structures or in various combinations to each other. Possible uses include:

- Luting of orthodontic anchors and brackets
- Luting of abutments to dentures
- Core build-up material
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for provisionals
- Bite registration material
- Build up material for plastic bite rails (occlusal individualisation).

PermaCem Dual:
PermaCem Dual is a dual cure (chemical and/or light cure), radiopaque two-component luting material available in automix delivery systems or as a handmix material, designed for the permanent luting of

metals, ceramics, and resin-based materials, which may be luted to tooth structures or in various combinations to each other. Possible uses include:

- Core build-up material
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for provisionals
- Bite registration material
- Build up material for plastic bite rails (occlusal individualisation).

Indications for Use:
PermaCem is a chemical cure compomer cement for permanent luting of metal, resin or ceramic crowns, bridges, inlays and onlays.

PermaCem Dual is a dual cure compomer cement for permanent luting of metal, resin or ceramic crowns, bridges, inlays and onlays.

PermaCem and PermaCem Dual can also be used for:

- Luting of orthodontic anchors and brackets
- Luting of abutments for dentures
- Core build-up
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for resin-based provisionals
- Bite registration material
- Occlusal individualisation of plastic bite rails

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), DMG USA, Inc. has provided information to demonstrate conformity with FDA's guidance document entitled ***Dental Cements - Premarket Notification***, August 1998 and ISO 4049 – Dentistry – Polymer-based filling, restorative and luting materials.

Conclusion:
Based on their indications for use, technological characteristics, and comparison to predicate devices, the PermaCem / PermaCem Dual materials have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

Ms. Pamela Papineau
Consultant
DMG USA, Incorporated
414 South State Street
Dover, Delaware 19901

Re: K012316
Trade/Device Name: Permacem/Permacem Dual
Regulation Number: 872.3275
Regulatory Class: II
Product Code: EMA
Dated: June 22, 2001
Received: July 23, 2001

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012316

510(k) Number (if known): K012316

Device Name: PermaCem / PermaCem Dual

Indications for Use:

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PermaCem Dual is a dual cure compomer cement for permanent luting of metal, resin, or ceramic crowns, bridges, inlays and onlays.

PermaCem Dual can also be used for:

- Luting of orthodontic anchors and brackets
- Luting of abutments for dentures
- Core build-up
- Splinting of teeth in combination with wires, Kevlar or Ribbond-type materials
- Repair material for resin-based provisionals
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012316

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